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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/602,350

06/23/2003

Jia-Hao Xiao

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21005

7590

10/20/2006

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.
530 VIRGINIA ROAD
P.O. BOX 9133
CONCORD, MA 01742-9133

EXAMINER

HARRIS, ALANA M

ART UNIT

PAPER NUMBER

1643

DATE MAILED: 10/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/602,350

Applicant(s)

XIAO ET AL.

Examiner

Alana M. Harris, Ph.D.

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 13 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 09/27/08; 06/23/03

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I (claims 1-13) in the reply filed on August 04, 2006 is acknowledged. The traversal is on the ground(s) that "[t]he methods of Groups I and II are related and are connected by design, operation and effect...", see Remarks, page 5. This is not found persuasive because the method objectives continue to be distinct as provided in the Requirement mailed March 24, 2006. The inventions of Groups I and II are materially different processes comprising different process steps, the material necessary to inhibit cellular proliferation would be different from the material necessary to determine if a test compound is an RXR agonist.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-14 are pending.

Claims 13 and 14, drawn to non-elected inventions, are withdrawn from examination.

Claims 1-12 are examined on the merits.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 9 is vague and indefinite for the recitation "...RXR protein is provided to said cell *by means of oral or rectal administration*". A cell is typically not regarded as having a defined orifice, hence supplying a protein through one of the openings corresponding to the specified administration is not well understood. It is not clear if Applicants intended for the administration to be delivered to a subject. Likewise, claim 10 reads on the systemic administration of a RXR ligand to a cell. Given systemic generally relates to a system, as in an entire organism as distinguished from any of its individual parts the systemic administration to a cell is indefinite. Applicants are requested to clarify.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-4 and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Kopf et al. (The Journal of Biological Chemistry 275(43): 33280-33288, 2000/ IDS reference AD submitted June 23, 2003). Kopf discloses the transfection of a COS-1 cells with RXR α 1 isoform and the further administration of pan-RXR-specific agonist

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(BMS649), see page33281, Results section, 2nd paragraph. The disclosed method reads on the claimed method steps, thereby anticipating the claimed invention.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kopf et al. (The Journal of Biological Chemistry 275(43): 33280-33288, 2000/ IDS reference AD submitted June 23, 2003), and further in view of U.S. Patent Application Publication number 2002/0004489 A1 (filed February 21, 2001). The teachings of Kopf have been presented in the 102(b) rejection. Kopf do not teach the RXR protein in viral derived vectors or the expression of said recombinant unit in a colon cancer cell.

However, the publication teaches retinoid X receptor proteins in a variety of host-expression vector systems, including adeno-associated viruses, see pages 46 and 47, sections 0415-0419. And the publication teaches cancers that can be treated with the administration of polynucleotides of the said invention such as colorectal cancer comprising colon cancer cells, see page 58, sections 0557 and 0558. It would have been *prima facie* obvious to one of ordinary skill in the art to implement the teachings of the patent. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings in the recited publications because

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both exemplified expression of the RXR proteins in a recombinant eukaryotic expression system.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571) 272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Alana M. Harris, Ph.D.
16 October 2006

**ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER**